

Notice of Allowability

Application No.

10/789,320

Examiner

Allison M. Ford

Applicant(s)

MARTIS ET AL.

Art Unit

1651

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to telephonic interview of 15 May 2006.
2. ☒ The allowed claim(s) is/are 45-58.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☐ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☒ Information Disclosure Statements (PTO-1449 or PTO/SB/08), Paper No./Mail Date _____
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☒ Interview Summary (PTO-413), Paper No./Mail Date _____
7. ☒ Examiner's Amendment/Comment
8. ☐ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____.

EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Mr. Thomas Basso on 15 May 2006.

The application has been amended as follows:

Please use the following version of claims:

Claims 1-44. (Cancelled)

Claim 45. A method for manufacturing a dialysis solution, the method comprising:

- a) providing a glucose polymer in a powder form;
- b) performing a modified bioburden test on the glucose polymer to detect contaminating *Alcyclobacillus acidocaldarius*;
- c) preparing a glucose polymer solution using the powder form of the glucose polymer;
- d) sterilizing the glucose polymer solution;
- e) adding a reagent derived from silkworm larvae plasma to the sterilized glucose polymer solution, wherein the reagent is reactive with peptidoglycan to determine a peptidoglycan concentration; and
- f) using the sterilized glucose polymer solution to prepare the dialysis solution if the peptidoglycan concentration is determined to be about 10 ng/mL or less.

Claim 46. The method of claim 45, wherein the reaction with the reagent initiates a serine protease cascade.

Claim 47. The method of claim 46, wherein the serine protease cascade includes a prophenol oxidase cascade.

Claim 48. The method of claim 45, wherein the peptidoglycan concentration is determined by a colorimetric measurement.

Claim 49. The method of claim 45, wherein the modified bioburden test includes testing for the *Alicyclobacillus acidocaldarius* at a pH of less than about 5.0.

Claim 50. The method of claim 45, wherein the modified bioburden test includes testing for the *Alicyclobacillus acidocaldarius* at a temperature of 50°C to 60°C.

Claim 51. The method of claim 45, wherein the glucose polymer includes icodextrin.

Claim 52. A method of testing a glucose polymer for peptidoglycan contamination, the method comprising:

- a) providing a glucose polymer in powder form;
- b) performing a modified bioburden test on the glucose polymer to detect *Alicyclobacillus acidocaldarius*, which is a source of peptidoglycan;
- c) preparing a glucose polymer solution using the powder form of the glucose polymer;
- d) sterilizing the glucose polymer solution; and
- e) adding a reagent derived from silkworm larvae plasma to the sterilized glucose polymer solution, wherein the reagent is reactive with peptidoglycan to determine a peptidoglycan concentration in the sterilized glucose polymer solution.

Claim 53. The method of claim 52, wherein the reaction with the reagent initiates a serine protease cascade.

Claim 54. The method of claim 53, wherein the serine protease cascade includes a prophenol oxidase cascade.

Claim 55. The method of claim 52, wherein the peptidoglycan concentration is determined by a colorimetric measurement.

Claim 56. The method of claim 52, wherein the modified bioburden test includes testing for the *Alicyclobacillus acidocaldarius* at a pH of less than about 5.0.

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Claim 57. The method of claim 52, wherein the modified bioburden test includes testing for the *Alicyclobacillus acidocaldarius* at a temperature of 50°C to 60°C.

Claim 58. The method of claim 52, wherein the glucose polymer includes icodextrin.


Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Allison M. Ford whose telephone number is 571-272-2936. The examiner can normally be reached on 7:30-5 M-Th, alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Allison M Ford
Examiner
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LEON B. LANKFORD, JR.
PRIMARY EXAMINER